FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
117th Meeting of the Blood Products Advisory Committee
Joint Meeting with the Medical Devices Advisory Committee (Microbiology Devices Panel)
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 22, 2018

DRAFT AGENDA

March 22, 2018

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Angela M. Caliendo, M.D., Ph.D., Acting Chair, BPAC
8:10 a.m.	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC

Topic III: Device reclassification from Class III to Class II of nucleic Acid and serology- based in vitro diagnostic devices indicated for use as aids in the diagnosis of hepatitis C virus (HCV) infection and/or for use of aids in the management of HCV infected patients

8:30-8:35 a.m.	Introduction to Topic/ Welcome	Uwe Scherf, Ph.D. CDRH, FDA (5')
8:35-8:45 a.m.	Reclassification Process Overview	Steve Gitterman, M.D. CDRH, FDA (10')
8:45-9:05 a.m.	HCV Disease – Diagnosis, clinical manifestations Health perspective	Arthur Kim, M.D. Harvard Medical School (20')
9:05-9:25 a.m.	Epidemiological and Public Health Perspective on HCV and HCV testing	Saleem Kamili, Ph.D. Centers for Disease of Control and Prevention (20')
9:25-9:40 a.m.	Questions to the speakers	(15')
9:40-10:00 a.m.	Break	(20')
10:00-10:20 a.m.	FDA perspective on reclassification of HCV Serology	Ines Garcia, Ph.D. CDRH, FDA (20')
10:20- 10:40 a.m.	FDA perspective on reclassification of HCV RNA Devices	Silke Schlottmann, Ph.D. CDRH, FDA (20')

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10:40-10:55 a.m.	Questions to FDA	(15')
10:55-11:55 p.m.	Open Public Hearing	(60')
12:00-1:00 p.m.	Lunch	(60')
1:00- 3:15 p.m.	Questions to the panel and deliberations	(135")
3:15- 3:20 p.m.	Summary and Adjourn	Uwe Scherf, Ph.D. CDRH, FDA (5')